

Response

U.S. Serial No. 09/805,217

Attorney Reference: 037003-0279190

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IN THE SPECIFICATION

At page 1, please substitute paragraph 1 as follows:

--This application claims priority from U.S. Serial No. 60/189,050, filed March 14, 2000, incorporated by reference herein.

A 2-NE
no mark-up

REMARKS

Entry of the foregoing amendments, reconsideration and re-examination of the subject application, as amended pursuant to and consistent with 37 CFR §1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendments, all of the claims are cancelled in favor of new claims 29-38. Support may be found at least in the examples which describe the use of unconjugated antibodies (particularly primate antibodies) having complement dependent cytotoxic (CDC) activity against a human tumor cell line SKW, a lymphoma cell line.

This amendment is consistent with Applicants' previous Election reply.

Turning now to the Office Action, Applicants confirm their previous Election. Claims 29-37 are all readable on the elected group.

The objection to the specification is noted. The correction of the filing date of the provisional application is made herein.

The rejection to claim 1 is moot as the new claims provide that the antibody is isolated, therefore obviating the §101 non-statutory issue.

The objection to claims 5-8 under 35 U.S.C. Section 112, second paragraph, as allegedly being indefinite due to the use of the phrase "treating tumors, neoplasms or cancer" is respectfully traversed. It is submitted that those of skill in the art can readily understand the metes and bounds of the claimed subject matter. However, claims 5-8 are canceled herewith and the new claims do not use this phraseology.

The rejection of claims 3 and 7 under 35 U.S.C. Section 112, first paragraph, as allegedly non-enabled is respectfully traversed. However, it is respectfully submitted that this rejection is moot as these claims are cancelled.

The rejection of claims 1-8 under 35 USC §102(e) as allegedly being anticipated by Thorpe is respectfully traversed. Claims 1-8 are canceled herewith and new claims 29-38

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substituted therefore. Accordingly, this rejection is believed to be obviated by the present amendment.

Applicant's invention as defined by claims 29-38 requires isolated antibodies that induce a complement dependent cell-mediated cytotoxicity against a human tumor cell that expresses phosphatidyl serine. While Thorpe purports to disclose monoclonal antibodies to aminophospholipids including phosphatidyl serine, potentially for therapy, it is clear that they envision the use of immunotoxins comprising a monoclonal antibody or binding fragment attached to a cytotoxic moiety. This is clear, e.g. from col. 2, wherein they summarize their invention in its broadest aspect, and expressly state that their invention "thus provides binding ligands and antibodies against aminophospholipids that are operatively attached to therapeutic agents."

Based on a fair interpretation of the patent, and based on their own admissions the inventors in Thorpe et al. do not disclose nor envision unconjugated monoclonal antibodies against phosphatidyl serine having complement dependent cytotoxic activity against human cells as claimed herein, or particularly human or primate antibodies having such activity. Only Applicant has discovered such antibodies. Therefore, withdrawal of the §102 rejection based on Thorpe is respectfully requested.

The rejection of claims 1 and 27 under 35 USC §102(b) as allegedly being anticipated by Maneta-Peyet et al. is respectfully traversed. Claims 1 and 27 are canceled herewith. Claim 1 is substituted by claim 29 and claim 27 has no counterpart in the presently pending claims. This rejection is traversed the reference does not teach or suggest an anti-phosphatidyl serine antibody that induces CDC activity against human cells as required by the presently pending claims. Withdrawal of the rejection is respectfully requested.

The rejection of claims under §102(b) as allegedly being anticipated by Vogt et al. is respectfully traversed. Claims 1 and 2 are canceled herewith and replaced by claim 29. This rejection is also traversed on the basis that the reference does not teach an isolated monoclonal that induces CDC activity against phosphatidyl serine expressing human tumor cells, as required by the presently pending claims. Rather it teaches mouse antibodies of the IgM isotype which are used as immunoprecipitating agents. As the reference is limited to diagnostic antibodies, it does not provide any incentive to produce antibodies having the CDC activity claimed herein.

The rejection of claims 1-3, 5-7 and 27 under 35 USC §102(b) as allegedly being anticipated by Umeda et al. is respectfully traversed. Claims 1-3, 5-7 and 27 are cancelled herewith and claims 29-38 substituted therefore. Umeda neither discloses nor suggests an isolated unconjugated monoclonal antibody that specifically binds phosphatidyl serine and that induces a complement dependent cell-mediated cytotoxicity against a human tumor cell that expresses phosphatidyl serine as required by the presently pending claims. Instead, this reference relates solely to high specificity antibodies produced in rabbits that are to be used diagnostically.

There is no teaching of an isolated monoclonal antibody inducing CDC activity against human tumor cells as required by presently pending claims 29-38. Accordingly, withdrawal of the rejection based on Umeda is respectfully requested.

Further, the rejection of claims 1-3, 5-7 and 27 under 35 USC §102(b) as allegedly being anticipated by Rote et al. is respectfully traversed. This traversal is similarly made on the basis that the teachings of the reference are limited to a diagnostic antibody produced in mice for immunodetection of phosphatidyl serine externalization. There is no suggestion of an unconjugated anti-phosphatidyl serine monoclonal antibody having or inducing CDC activity against human tumor cells as claimed herein. Withdrawal of the rejection based on Rote is therefore requested.

Finally, the rejection of claims 1-8 and 27-28 under 35 USC §103(a) based on Thorpe et al. in view of Harlow et al. is respectfully traversed.

Thorpe et al. has been discussed above. The reference does not fairly suggest the claimed invention as it provides no teaching or suggestion as to monoclonal antibodies specific to phosphatidyl serine that exhibit CDC activity against human tumor cells, particularly human lymphoma cells, as required by the presently pending claims. Rather, the reference is limited to the use of anti-aminophospholipid antibodies for targeting toxic agents to specific cells.

Harlow is a general teaching reference relating to antibody assay, i.e. ELISA's. However, this reference is otherwise irrelevant to the invention.

Thus, withdrawal of the §103 rejection based on Thorpe in view of Harlow is respectfully requested.

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Based on the foregoing, allowance of this application is believed to be in order. A Notice to that effect is respectfully solicited.

Respectfully submitted,

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